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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,818	10/07/2003	Jorge R. Barrio	50319/KMO/R268	5364

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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT PAPER NUMBER

1618

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,818

Applicant(s)

BARRIO ET AL.

Examiner

Jagadishwar R. Samala

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/18/2004

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrio et al., (J. Am Chem. Soc., 1996, 118, 5572-5579). Barrio discloses synthesis of a novel fluorophore 1,1-Dicyano-2-[6-(dimethylamino)naphthalene-2-yl] propene (DDNP) a fluorescent dye having excellent properties for visible wavelength fluorescence microscopy using standard argon or conventional lamp sources. Barrio also discloses development of the fluorescent DDNP dye as a neutral lipophilic probe and since it is an uncharged molecule at physiological pH, it can cross membrane barriers, and when linked to a molecule of biological interest, it can be used to study intracellular in vivo processes.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1- 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrio et al., (J. Am Chem. Soc., 1996, 118, 5572-5579), in view of Triplett et al.,(US 4,256,727 here after '727) in further view of Kung (US 5,609,849 here after '849).
 5. Claims 1-5 are drawn to a composition comprising a compound, wherein one or more of the hydrogen, halogen or carbon atoms are optionally replaced with a radiolabel.
 6. The Barrio publication discloses a method of synthesizing a fluorescent dye molecule 1,1-Dicyano-2-[6-(dimethylamino)naphthalene-2-yl] propene (DDNP) as a neutral lipophilic probe and when linked to a molecule of biological interest, it can be used to study intracellular in vivo processes.
 7. The Barrio publication fails to teach specifically radio labeling the fluorescent dye (DDNP) for in vitro detection of Alzheimer's disease, i.e., with ^{18}F or ^{123}I .
 8. The '727 patent discloses a process for producing a diagnostic radiopharmaceutical product labeled with a radioactive halogen, and the products thereof which is useful as a diagnostic radio-pharmaceutical (see column 1, lines 8-23), which provides the advantage of radio detection.
- The '849 patent discloses a composition comprising a compounds that are highly selective for serotonin (5-HT_{1A}) receptor, as imaging agents (see column 7, lines

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28-30). The prior art provides tools of powerful imaging methods, which enable one to assess the living brain in vivo and thereby monitor the effectiveness of drugs and substances that affect brain chemistry. The use of radioisotopes to label organic compounds for use in diagnostic nuclear medicine is well documented in the literature (US 5,098,996 see column 7, lines 5-20 and column 11-12, scheme 6). Radioactive fluorine (^{18}F) can be easily introduced into biologically active molecules containing amino groups e.g. process for introducing radioactive fluorine into biologically active molecule for use in diagnostic nuclear medicine and is taught to be equivalent to ^{76}Br , ^{77}Br or ^{82}Br which is taught by '727 (see column 7, lines 45-60).

9. It would have been obvious to one of ordinary skill in the art to radio label the fluorescent dye of Barrio, because it is known in the art that such fluorescent dyes may be labeled with radioisotopes to provide the advantage of radio detection as taught by '727 which teaches use ^{76}Br , ^{77}Br or ^{82}Br . Further it would have been obvious to substitute radioisotope bromine with ^{18}F or (^{123}I) successfully in diagnostic nuclear medicine as imaging agents to visualize abnormalities and to determine the function thereof, so as to treat or prevent such conditions and diseases. Further it would have been obvious to one of ordinary skill in the art to modify the radio labeled imaging agents of '727 and '849 which may be injected intravenously into the patient. Following injection, the nervous system is monitored using equipments such as positron emission tomography (PET) and single photon emission tomography (SPECT), which maps radioisotope distribution within the human body. Digital data can also be

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stored on magnetic tape, allowing computer processing to provide graphs showing activity variations with time in selected areas of the scan.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

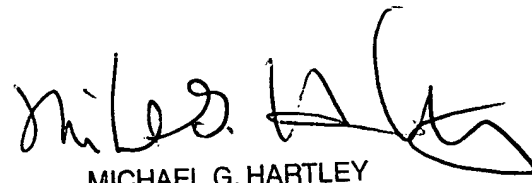
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service

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Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER